UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,955	04/15/2004	Kenneth T. Heruth	1023-362US01	8230

28863 7590 07/20/2006

SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 07/20/2006

D: 10-20-06 bmd

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/825,955	HERUTH ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-42 and 44-68* is/are pending in the application.

4a) Of the above claim(s) *7,10,12-15,17-20,28-42 and 44-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8,9,11 and 17-27* is/are rejected.

7)☒ Claim(s) *11 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

hment(s)

otice of References Cited (PTO-892)

e of Draftsperson's Patent Drawing Review (PTO-948)

tion Disclosure Statement(s) (PTO-1449 or PTO/SB/08)

(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 06/30/2006, amended claims 1, 26, 28, 42, 57, and 65 and canceled claims 16 and 43 are acknowledged.

Election/Restrictions

2. Applicant's election with traverse of Group I in the reply filed on 06/30/2006 is acknowledged. The traversal is on the ground(s) that no serious burden exists because many of the dependent claims are substantially similar and that materially different processes have not been provided. This is not found persuasive because Groups I-III differ widely in scope and Groups II and III can be used to practice materially different processes such as periodically determining, monitoring, tracking, and displaying the three-dimensional spatial orientation of a patient via the plurality of orthogonally aligned accelerometers for use in rehabilitation analysis in a post-surgical biomechanic-correction procedure, tracking and studying the tic biomechanical motion of patients with Tourette's syndrome, and/or monitoring trembling associated with Parkinson's disease.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 28-42 and 44-68 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable

generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 06/30/2006.

4. Applicant's election without traverse of Species B in the reply filed on 06/30/2006 is acknowledged. Claims 7, 10, 12-20, 34, 37, and 39-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2006.

5. The examiner notes applicant indicated that claims 17-20 were drawn to Species B and therefore ready for examination however claims 17-20 are withdrawn as being dependent upon withdrawn claims.

6. Applicant's election without traverse of Species BB in the reply filed on 06/30/2006 is acknowledged. Claim 63 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2006.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

8. The information disclosure statement(s) (IDS) submitted on 04/07/2005, 09/26/2005, 09/29/2005, 03/21/2006, and 06/16/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

9. The examiner notes the following: Non-Patent Literature submission cited Michael T. Smith et al., "How do sleep disturbance and chronic pain inter-related?", Sleep Medicines Reviews, YSMRV 286-19/6/2003 was of poor quality and illegible in areas and thus not considered; resubmission is encouraged.

Claim Objections

10. Claim 11 is objected to because of the following informalities: claim 11 positively recites the limitation "the sleep quality metric" in lines 1-2, there appears to be insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

11. Claim 22 is objected to because of the following informalities: claim 22 positively recites the limitation "the medical device" in line 1, there appears to be insufficient antecedent basis for this limitation in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1-6, 8, 9, 11, and 21-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Park et al (US 6,351,672 B1). Park et al discloses a method, comprising:

- monitoring a plurality of physiological parameters of a patient via a medical device (10), wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity (column 3 lines 6-25 and lines column 5 lines 23-47);
- determining when the patient is attempting to sleep (Figure 5 and column 7 lines 24-31);
- determining values of at least one metric (the transfer function as best seen in Figure 2) that is indicative of sleep quality based on at least one of the physiological parameters, a determination that the patient is attempting to sleep, on the determined activity level; and
- periodically determining an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep (column 7 lines 10-24 and 31-61).

14. For claim 2, Park et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the sensed activity levels via sensor 68) from the patient that the patient is attempting to sleep (column 7 lines 24-31).

15. For claims 3 and 4, Park et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep comprises determining when the patient is recumbent (column 7 line 10 – column 8 lines 31) and (b) a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent comprises determining when the patient is recumbent based on a DC component of each of the signals (column 2 lines 51-65 and column 3 lines 6-27).

16. For claims 5 and 6, Park et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (column 7 lines 24-31) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (column 3 lines 33 – 39 and column 6 line 54 – column 7 line 9).

17. For claims 8 and 9, Park et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood oxygen saturation (column 3 lines 6-28).

18. For claim 11, Park et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the

physiological parameters; and determining an amount of time between the first and second times (column 3 lines 33-39 and column 7 lines 10-19).

19. For claims 21-23, Park et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (column 6 line 65 – column 7 line 19); (b) a medical device delivers a therapy (the pacing signals delivered by the A-pulse generator 22 and the V-pulse generator 24) to the patient according to a plurality of therapy parameter sets, the method further comprising: associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set; for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set as best seen in Figures 2 and 5; and (c) presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values (column 6 line 65 – column 7 line 19).

20. For claim 25, Park et al discloses a method wherein a medical device comprises an implantable medical device (10).

Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park et al in view of Cho et al (US 6,964,641 B2). Park et al discloses the claimed methods of using an implantable medical device including an implantable neurostimulator (10) except for implanting and/or utilizing a drug pump. Cho et al teaches a method of using an implantable medical device (10) with a drug pump (column 4 lines 46-59, column 9 lines 22-30, and column 10 lines 12-17). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method of using an implantable medical device as taught by Park et al, with the drug pump of Cho et al for the purpose of configuring an implantable medical device responsive to patient sleeping and posture so as to increase the efficacy of the device to respond to a patient's physical activity levels.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JGH

MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth T. Heruth; Keith A. Miesel	Confirmation No.	8230
Serial No.:	10/825,955		
Filed:	April 15, 2004	Customer No.:	28863
Examiner:	Jeffrey Gerben Hoekstra		
Group Art Unit:	3736		
Docket No.:	1023-362US01		
Title:	COLLECTING ACTIVITY AND SLEEP QUALITY INFORMATION VIA A MEDICAL DEVICE		

AMENDMENT

Mail Stop Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action mailed July 20, 2006, the period of response for which runs through October 20, 2006, please amend the application as follows.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 15 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claim 1 (Currently Amended): A method comprising:

monitoring a plurality of physiological parameters of a patient via a medical device, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity;

determining when the patient is attempting to sleep;

determining values of at least one sleep quality metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep;

periodically determining an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep; and

determining a value of at least one activity metric based on the determined activity level.

Claim 2 (Original): The method of claim 1, wherein determining when the patient is attempting to sleep comprises receiving an indication from the patient that the patient is attempting to sleep.

Claim 3 (Original): The method of claim 1, wherein monitoring a plurality of physiological parameters comprising monitoring at least one signal that indicates posture of the patient, and determining when the patient is attempting to sleep comprises determining when the patient is recumbent.

Claim 4 (Original): The method of claim 3, wherein monitoring at least one signal comprises monitoring a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent comprises determining when the patient is recumbent based on a DC component of each of the signals.

Claim 5 (Original): The method of claim 1, wherein determining when the patient is attempting to sleep comprises determining when the patient is attempting to sleep based on a physical activity level of the patient.

Claim 6 (Original): The method of claim 5, wherein determining when the patient is attempting to sleep based on activity level comprises:

comparing the activity level to an activity level threshold; and

comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold.

Claim 7 (Withdrawn): The method of claim 1, wherein monitoring a plurality of physiological parameters comprising monitoring a level of melatonin within a bodily fluid, and determining when the patient is attempting to sleep comprises determining when the patient is attempting to sleep based on the melatonin level.

Claim 8 (Currently Amended): The method of claim 1, wherein monitoring a plurality of physiological parameters comprises monitoring at least one of posture, heart rate, respiration rate, respiratory volume, ~~and~~ or core temperature.

Claim 9 (Currently Amended): The method of claim 1, wherein monitoring a plurality of physiological parameters comprises monitoring at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, ~~and~~ or galvanic skin response.

Claim 10 (Withdrawn): The method of claim 1, wherein the sleep quality metric comprises sleep efficiency, and determining values of the sleep quality metric comprises:

determining when the patient is asleep based on at least one of the physiological parameters; and

determining a percentage of time that the patient is asleep while the patient is attempting to sleep.

Claim 11 (Original): The method of claim 1, wherein the sleep quality metric comprises sleep latency, and determining values of the sleep quality metric comprises:

identifying a first time when the patient is attempting to fall asleep;

identifying a second time when the patient falls asleep based on at least one of the physiological parameters; and

determining an amount of time between the first and second times.

Claim 12 (Original): The method of claim 1, wherein determining values of the sleep quality metric comprises:

identifying when the patient is asleep based on at least one of the physiological parameters; and

determining an amount of time that the patient is asleep during a period.

Claim 13 (Withdrawn): The method of claim 1, wherein determining values of the sleep quality metric comprises:

identifying when the patient is asleep based on at least one of the physiological parameters; and

identifying at least one of a number of arousal events and a number of apnea events during a period of sleep.

Claim 14 (Original): The method of claim 1, wherein determining values of the sleep quality metric comprises:

identifying when the patient is within a sleep state based on at least one of the physiological parameters; and

determining an amount of time that the patient was within the sleep state.

Claim 15 (Original): The method of claim 14, wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state.

Claim 16 (Cancelled).

Claim 17 (Currently Amended): The method of claim ~~15~~ 1, wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels.

Claim 18 (Original): The method of claim 17, wherein determining a value of an activity metric comprises:

comparing the at least one of the mean and the median activity level to at least one threshold; and

selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison.

Claim 19 (Currently Amended): The method of claim ~~15~~ 1, wherein determining a value of an activity metric comprises:

comparing each of the activity levels to a threshold value; and

determining at least one of a percentage of time above the threshold and a percentage of time below the threshold.

Claim 20 (Currently Amended):The method of claim ~~15~~ 1, wherein determining a value of an activity metric comprises:

comparing each of the activity levels to a threshold value; and

determining an average length of time that consecutively determined activity levels were above the threshold.

Claim 21 (Original): The method of claim 1, wherein periodically determining an activity level comprises periodically determining a number of activity counts.

Claim 22 (Original): The method of claim 1, wherein the medical device delivers a therapy to the patient according to a plurality of therapy parameter sets, the method further comprising:

associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set;

for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and

for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

Claim 23 (Original): The method of claim 22, further comprising presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values.

Claim 24 (Original): The method of claim 23, further comprising ordering the list of therapy parameter sets according to values of a user selected one of the sleep quality metrics and activity metrics.

Claim 25 (Original): The method of claim 1, wherein the medical device comprises an implantable medical device.

Claim 26 (Previously Presented): The method of claim 25, wherein the implantable medical device comprises at least one of an implantable neurostimulator and an implantable drug pump.

Claim 27 (Original): The method of claim 1, wherein the medical device comprises at least one of a trial neurostimulator and a trial pump.

Claim 28 (Withdrawn): A medical system comprising:

a medical device that monitors a plurality of physiological parameters of a patient, wherein the plurality of physiological parameters includes at least one physiological parameter indicative of patient physical activity; and

a processor that determines when the patient is attempting to sleep, determines values of at least one metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep, periodically determines an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep, and determines a value of at least one activity metric based on the determined activity levels.

Claim 29 (Withdrawn): The medical system of claim 28, wherein the processor receives an indication from the patient that the patient is attempting to sleep.

Claim 30 (Withdrawn): The medical system of claim 28, wherein the medical device monitors at least one signal that indicates posture of the patient, and the processor determines when the patient is attempting to sleep by determining when the patient is recumbent.

Claim 31 (Withdrawn): The medical system of claim 30,

further comprising a plurality of orthogonally aligned accelerometers,

wherein the medical device monitors a signal from each of a plurality of orthogonally aligned accelerometers, and the processor determines when the patient is recumbent based on a ~~DC~~ component of each of the signals.

Claim 32 (Withdrawn): The medical system of claim 28, wherein the processor determines when the patient is attempting to sleep based on a physical activity level of the patient.

Claim 33 (Withdrawn): The medical system of claim 32, wherein the processor compares the activity level to an activity level threshold, and compares an amount of time that the activity level remains substantially below the activity level threshold to a time threshold to determine when the patient is attempting to sleep.

Claim 34 (Withdrawn): The medical system of claim 28, wherein the medical device monitors at least one signal that indicates a level of melatonin within a bodily fluid of the patient, and the processor determines when the patient is attempting to sleep based on the melatonin level.

Claim 35 (Withdrawn): The medical system of claim 28, wherein the medical device monitors at least one of posture, heart rate, respiration rate, respiratory volume, and core temperature.

Claim 36 (Withdrawn): The medical system of claim 28, wherein the medical device monitors at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, and galvanic skin response.

Claim 37 (Withdrawn): The medical system of claim 28, wherein the sleep quality metric comprises sleep efficiency, and the processor determines when the patient is asleep based on at least one of the physiological parameters, and determines a percentage of time that the patient is asleep while the patient is attempting to sleep as a value of the sleep quality metric.

Claim 38 (Withdrawn): The medical system of claim 28, wherein the sleep quality metric comprises sleep latency, and the processor identifies a first time when the patient is attempting to fall asleep, identifies a second time when the patient falls asleep based on at least one of the physiological parameters, and determines an amount of time between the first and second times as a value of the sleep quality metric.

Claim 39 (Withdrawn): The medical system of claim 28, wherein the processor identifies when the patient is asleep based on at least one of the physiological parameters, and determines an amount of time that the patient is asleep during a period as a value of the sleep quality metric.

Claim 40 (Withdrawn): The medical system of claim 28, wherein the processor identifies when the patient is asleep based on at least one of the physiological parameters, and identifies at least one of a number of arousal events and a number of apnea events during a period of sleep as a value of the sleep quality metric.

Claim 41 (Withdrawn): The medical system of claim 28, wherein the processor identifies when the patient is within a sleep state based on at least one of the physiological parameters, and determines an amount of time that the patient was within the sleep state as a value of the sleep quality metric.

Claim 42 (Withdrawn): The medical system of claim 41, wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state.

Claim 43 (Canceled)

Claim 44 (Original): The medical system of claim 43, wherein the processor determines an activity metric value as at least one of a mean and a median of determined activity levels.

Claim 45 (Withdrawn): The medical system of claim 43, wherein the processor compares the at least one of a mean and a median activity level to at least one threshold, and selects the activity metric value from a plurality of predetermined possible activity metric values based on the comparison.

Claim 46 (Withdrawn): The medical system of claim 43, wherein the processor compares each of the activity levels to a threshold value, and determines at least one of a percentage of time above the threshold and a percentage of time below the threshold as an activity metric value.

Claim 47 (Withdrawn): The medical system of claim 43, wherein the processor compares each of the activity levels to a threshold value, and determines an average length of time that consecutively determined activity levels were above the threshold as an activity metric value.

Claim 48 (Withdrawn): The medical system of claim 28, wherein the processor periodically determines an activity level be periodically determining a number of activity counts.

Claim 49 (Withdrawn): The medical system of claim 28,

wherein the medical device delivers a therapy to the patient according to a plurality of therapy parameter sets,

wherein the processor associates each of the determined sleep quality metric value and each of the determined activity levels with a current therapy parameter set,

wherein, for each of the plurality of therapy parameter sets, the processor determines a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set, and

wherein, for each of the plurality of therapy parameter sets, the processor determines at least one activity metric value based on the activity levels associated with the therapy parameter set.

Claim 50 (Withdrawn): The medical system of claim 49, further comprising a programming device including a display that presents a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values.

Claim 51 (Withdrawn): The medical system of claim 50, wherein the programming device receives user selection of one of the sleep quality metrics and activity metric, and orders the list of therapy parameter sets according to values of the user selected one of the sleep quality metrics and activity metrics.

Claim 52 (Withdrawn): The medical system of claim 28, wherein the processor comprises a processor of the medical device.

Claim 53 (Withdrawn): The medical system of claim 28, further comprising a programming device, wherein the processor comprises a processor of the programming device.

Claim 54 (Withdrawn): The medical system of claim 28, wherein the medical device comprises an implantable medical device.

Claim 55 (Withdrawn): The medical system of claim 54, wherein the implantable medical device comprises at least one of an implantable neurostimulator and an implantable drug pump.

Claim 56 (Withdrawn): The medical system of claim 28, wherein the medical device comprises at least one of a trial neurostimulator and a trial pump.

Claim 57 (Withdrawn): A medical system comprising:

means for monitoring a plurality of physiological parameters of a patient via a medical device, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity;

means for determining when the patient is attempting to sleep;

means for determining values of at least one metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep;

means for periodically determining an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep; and

means for determining a value of at least one activity metric based on the determined activity levels.

Claim 58 (Withdrawn): The medical system of claim 57, wherein means for determining when the patient is attempting to sleep comprises means for receiving an indication from the patient that the patient is attempting to sleep.

Claim 59 (Withdrawn): The medical system of claim 57,

wherein means for monitoring a plurality of physiological parameters comprises means monitoring at least one signal that indicates posture of the patient, and

wherein means for determining when the patient is attempting to sleep comprises means for determining when the patient is recumbent.

Claim 60 (Withdrawn): The medical system of claim 57, wherein means for determining when the patient is attempting to sleep comprises means for determining when the patient is attempting to sleep based on a physical activity level of the patient.

Claim 61 (Withdrawn): The medical system of claim 57, further comprising:

means for delivering a therapy to the patient according to a plurality of therapy parameter sets;

means for associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set;

means for determining a representative value of each of the at least one sleep quality metric for each of the plurality of therapy parameter sets based on the sleep quality metric values associated with the therapy parameter sets;

means for determining at least one activity metric value for each of the plurality of therapy parameter sets based on the activity levels associated with the therapy parameter sets; and

means for presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values.

Claim 62 (Withdrawn): A medical system comprising:

an implantable medical device that delivers a therapy to a patient based on a plurality of therapy parameter sets, monitors a plurality of physiological parameters of the patient including at least one parameter indicative of patient physical activity, determines when the patient is attempting to sleep, determines values of at least one metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep, periodically determines an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep, associates each determined sleep quality metric value and each determined activity level with a current therapy parameter set, determines a representative value of each of the at least one sleep quality metrics for each of the plurality of therapy parameter sets based on the sleep quality metric values associated with the therapy parameter set, and determines at least one activity metric value for each of the plurality of therapy parameter sets based on the activity levels associated with the therapy parameter set; and

an external programming device including a display that receives information identifying the plurality of therapy parameter sets and the sleep quality metric values and activity metric values associated with the therapy parameter sets from the implantable medical device, and presents a list of the therapy parameter sets and the associated sleep quality metric values and activity metric values to a user.

Claim 63 (Withdrawn): The medical system of claim 62, wherein the programming device includes a user interface, receives a selection of one of the sleep quality metrics and activity metrics from a user via the user interface, and orders the list of therapy parameter sets according to the associated sleep quality metric values.

Claim 64 (Withdrawn): The medical system of claim 62, wherein the implantable medical device comprises at least one of an implantable neurostimulator and an implantable drug pump.

Claim 65 (Withdrawn): A computer-readable medium comprising instructions that cause a programmable processor to:

monitor a plurality of physiological parameters of a patient, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity; determine when the patient is attempting to sleep;

determine values of at least one metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep;

periodically determine an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep; and

determines a value of at least one activity metric based on the determined activity levels.

Claim 66 (Withdrawn): The medium of claim 65, wherein the instructions that cause the processor to determine when the patient is attempting to sleep comprise instructions that cause the processor to receive an indication from the patient that the patient is attempting to sleep.

Claim 67 (Withdrawn): The medium of claim 65, wherein the instructions that cause the processor to monitor a plurality of physiological parameters comprise instructions that cause the processor to monitor at least one signal that indicates posture of the patient, and the instructions that cause the processor to determine when the patient is attempting to sleep comprise instructions that cause the processor to determine when the patient is recumbent.

Claim 68 (Withdrawn): The medium of claim 65, wherein the instructions that cause the processor to determine when the patient is attempting to sleep comprise instructions that cause the processor to determine when the patient is attempting to sleep based on a physical activity level of the patient.

REMARKS

This Amendment is responsive to the Office Action dated July 20, 2006. Applicant has amended claims 1, 8, 9, 17, 19 and 20.

Pending and Withdrawn Claims

In the previous Response, Applicant provisionally elected Group I, Species B, and Species BB. Applicant erroneously indicated that claims 12, 14 and 15 did not read on Species B, and were thus withdrawn from further consideration. However, claims 12, 14 and 15 do read on species B, because they do not recite limitations specific to non-elected species A, C and D.[1] Accordingly Applicant respectfully submits that claims 1-6, 8, 9, 11, 12 and 14-27 read on the combination of Group I, Species B, and Species BB.

Furthermore, in the previous response, Applicant indicated that claims 17-20 were readable on species B. The Office Action indicated that claims 17-20 were nonetheless withdrawn because they depended from claim 15, which was withdrawn. As discussed above, Applicant erroneously indicated that claim 15 was not readable on elected species B. Therefore, claim 15 should not be withdrawn. Moreover, Applicant has amended claims 17, 19 and 20 to depend from independent claim 1, rather than claim 15. Therefore, claims 17-20 no longer depend from claim 15, and should no longer be considered withdrawn.

In sum, Applicant respectfully submits that claims 1-15, 17-42 and 44-68 are pending, with claims 7, 10, 13, 28-42 and 44-68 being withdrawn. In other words, Applicant respectfully submits that claims 1-6, 8, 9, 11, 12 and 14-27 should be examined. Applicant apologizes for any inconvenience due to the erroneous indication that claims 12, 14 and 15 did not read on Species B.

Information Disclosure Statement

The Office Action indicated that the reference, Michael T. Smith et al., "How do sleep disturbance and chronic pain inter-relate? Insights from the longitudinal and cognitive-behavioral clinical trials literature", Sleep Medicines Reviews, YSMRV 286-19/6/2003, from the Information Disclosure Statement filed April 5, 2005, was not considered due to poor quality and

[1] *See* MPEP § 806.04(e) and (f).

illegibility of the submitted copy. Applicant is seeking a cleaner copy of the reference, and will resubmit the reference as soon as one is found.

Claim Objections

The Office Action stated that there appeared to be insufficient antecedent basis for the limitation "the sleep quality metric" in claim 11. Claim 11 depends from claim 1. As previously presented, claim 1 recited, "determining values of at least one metric that is indicative of sleep quality." Applicant has amended claim 1, for purposes of clarification, to recite, "determining values of at least one sleep quality metric that is indicative of sleep quality." Applicant submits that claim 1, as amended, provides sufficient antecedent basis for the limitation "the sleep quality metric" in claim 11. Accordingly, Applicant requests withdrawal of the objection to claim 11.

The Office Action also stated that there appeared to be insufficient antecedent basis for the limitation "the medical device" in claim 22. Claim 22 depends upon claim 1. In line 2, claim 1 recites "monitoring a plurality of physiological parameters of a patient via a medical device" in line 2. Thus, Applicant respectfully submits that there was sufficient antecedent basis for the limitation "the medical device" in claim 22 as originally filed, Applicant requests withdrawal of the objection to claim 22.

Claim Rejection Under 35 U.S.C. § 102

The Office Action rejected claims 1-6, 8, 9, 11, and 21-27 under 35 U.S.C. § 102(b) as being anticipated by Park et al. (US 6,351,672, herein referred to as Park). Applicant respectfully traverses the rejection. Park fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Park fails to disclose or suggest determining when the patient is attempting to sleep, as recited by independent claim 1. The Office Action characterized Park's FIG. 5 as teaching this requirement. However, Park's FIG. 5 is merely a flow chart that illustrates how to monitor a patient's activity level and the variance of the activity level to determine when a patient transitions from a prolonged resting state to an active state. Specifically, Park is

interested in determining when orthostatic compensation therapy is needed to respond to a patient standing up after a prolonged resting period.

First, Park compares the patient's activity level to an activity threshold to determine if the patient is active or inactive.[2] If the patient is determined to be inactive, the variance in the activity level is compared to a variance threshold to determine if the patient is resting or simply inactive.[3] When a patient transitions from a prolonged resting state, such as a prolonged sitting, lying down, or standing position, to an active state an increased pacing rate is delivered to provide orthostatic compensation therapy to the patient.[4]

Park does not disclose or suggest determining when a patient is attempting to sleep. Park is not at all concerned with whether or not the patient is attempting to sleep. Instead, Park is limited to determining whether the patient is resting, and concerned with identifying the time at which the patient transitions to an active state to determine when to deliver orthostatic compensation therapy.

Moreover, Park fails to disclose or suggest determining values of at least one sleep quality metric that is indicative of sleep quality based on at least one of the physiological parameters and a determination that the patient is attempting to sleep, as further required independent claim 1, as amended. Since Park does not disclose or suggest determining when a patient is attempting to sleep, Park also does not disclose or suggest determining a value of a sleep quality metric based on at least one of the physiological parameters and a determination that the patient is attempting to sleep. As discussed above, Park is only concerned with whether the patient is resting.

Further, Park does not disclose determining anything remotely related to sleep quality when the patient is resting. Instead, Park merely describes delivering a pacing at a base rate and continuing to monitor activity to determine when the patient transitions to an active state to determine when to deliver orthostatic compensation therapy. Neither of these activities even suggests determining values of at least one sleep quality metric that is indicative of sleep quality, as required by independent claim 1.

---

[2] Park, figure 5, reference number 502.
[3] Park, figure 5, reference number 504.
[4] Park, abstract.

The Office Action cited the transfer function of Park's FIG. 2 as illustrating the determination of at least one sleep quality metric. The transfer function described by Park defines a relationship between the pacing rate and activity level. More specifically, if the activity level is below the low activity threshold, pacing is set at the base rate. Additionally, the pacing rate is set at the maximum pacing rate, if the activity level is above the high activity threshold, and the pacing rate is set between the base rate and the maximum pacing rate, if the activity level is between the low and high activity thresholds.

The transfer function described by Park is in no way indicative of sleep quality or related to determining a metric indicative of sleep quality. The transfer function is used to determine a pacing rate based on a patient's activity level, and does not determine a metric indicative of sleep quality.

With respect to Applicant's claim 4, Park fails to disclose or suggest monitoring a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent based on a DC component of each of the signals. Park discusses U.S. Patent No. 5,354,317 to Alt, which uses a DC accelerometer to determine whether a sleep base rate or a rest base rate should be used. Park states that the DC accelerometer of Alt cannot differentiate between the patient lying on the left or right side and standing, or detect the difference between standing and sitting.[5] Park teaches using a single AC accelerometer, rather than a DC accelerometer, to detect patient activity over time.[6] Thus Park teaches away from using a DC accelerometer.

Park fails to mention a plurality orthogonally aligned accelerometers whatsoever, and instead suggests using a single AC accelerometer to detect patient activity. Thus, Park fails to disclose or suggest using more than one accelerometer, and further fails to disclose or suggest using orthogonally aligned accelerometers. For at least these reasons, Park fails to disclose or suggest monitoring a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent based on a DC component of each of the signals, as required by Applicant's claim 4.

[5] Park, column 2, lines 41-54.
[6] Park, column 3, lines 17-20.

Park also fails to disclose or suggest determining values of a sleep quality metric by identifying a first time when the patient is attempting to fall asleep, identifying a second time when the patient falls asleep based on at least one of the physiological parameters, and determining an amount of time between the first and second times, as required by Applicant's claim 11. As described previously in this Amendment, Park fails to disclose or suggest identifying when a patient is attempting to fall asleep. Instead, Park describes monitoring a patient's activity level and the variance in the activity level to determine when the patient goes from a prolonged state of rest to an active state.

In addition to failing to determine when a patient is attempting to sleep, Park also fails to disclose or suggest determining an amount of time between when the patient attempts to fall asleep and when the patient falls asleep. Col. 3, ll. 33-39 and col. 7, ll. 10-19 of Park, cited in the Office Action, are not relevant to this requirement. Instead, the cited portions are merely related to determining whether the patient is resting rather than merely inactive, such that orthostatic compensation will be provided once the patient stands. The cited portions provide no teaching relating to determining whether the patient is asleep, or determining an amount of time between when the patient attempts to fall asleep and when the patient falls asleep. For at least these reasons, Park fails to disclose or suggest all of the requirements of Applicant's claim 11.

With respect to Applicant's claim 22, Park fails to disclose or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set, and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

In support of the rejection of claim 22, the Examiner cited FIGS. 2 and 5 of Park's disclosure. As discussed earlier in this Amendment, Park fails to disclose or suggest determining a sleep quality metric. The transfer function of Park's FIG. 2 is in no way related to sleep quality metrics. Instead, the transfer function is used to determine a pacing rate based on a patient's activity level. The transfer function described by Park does not associate each of the determined

sleep quality metric values and each of the determined activity levels with a current therapy parameter set. In fact, there are no determined sleep quality metric values in the Park system.

Additionally, Park's FIG. 5 does not discuss or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set. Park's FIG.5 is a flow chart illustrating how to determine if orthostatic pacing is needed based on the activity level of a patient and the variance of the activity level. Park's FIG. 5 indicates how to determine therapy parameters based on the activity level of the patient and the variance of the activity level by first measuring an activity and variance level and then, if necessary, adjusting the pacing rate.

In contrast, Applicant's claim 22 requires that when a sleep quality metric value or an activity level is determined, the therapy parameter set that was currently used to deliver stimulation is associated with the sleep quality metric value or activity level. In this manner, sleep quality and activity metrics may be used to, evaluate the effectiveness of the therapy parameters in some embodiments according to the claim.[7]

Park et al. fails to disclose each and every limitation set forth in claims 1, 4, 11 and 22. Claims 2, 3, 5, 6, 8, 9, 21 and 23-27 are dependent upon claim 1, and are also in condition for allowance. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-6, 8, 9, 11, and 21-27 under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Office Action, the Examiner rejected claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Park et al. in view of Cho et al. (US 6,964,641 B2, herein referred to as Cho). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Applicant traverses the rejection of claims 26 and 27 under 35 U.S.C. § 103(a) as being unpatentable over Park in view of Cho. Claims 26 and 27 are dependent upon claim 1. Park fails to disclose or suggest the requirements of claim 1 for at least the reasons stated previously in

[7] *See* Summary of Invention of present application.

this Amendment. Cho lacks any teaching sufficient to overcome the basic deficiencies described above with respect to Park. Therefore, claims 26 and 27 are also in condition for allowance. Withdrawal of this rejection is requested.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 26 and 27 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Applicant recognizes that claims 12, 14, 15 and 17-20 have not yet been examined. Applicant reserves comment regarding the applicability of the applied references to these claims at this time.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 10/20/06

By: _____

Name: Jason D. Kelly
Reg. No.: 54,213

SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,955	04/15/2004	Kenneth T. Heruth	1023-362US01	8230

28863 7590 01/17/2007
SHUMAKER & SIEFFERT, P. A.
8425 SEASONS PARKWAY
SUITE 105
ST. PAUL, MN 55125

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

D: 3-17-07 bmd pab

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,955	HERUTH ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-42 and 48-68* is/are pending in the application.

4a) Of the above claim(s) *7,10,13,28-42 and 48-68* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,17-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date: _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 10/20/2006, amended claims 1, 8, 9, 17, 19, and 20 are acknowledged. The current rejections of the claim(s) 1-6, 8, 9, 11, and 21-27 is/are *withdrawn*.

2. The examiner acknowledges applicant's remarks concerning applicant's erroneous withdrawal of claims 12, 14, and 15. Thus, claims 12, 14, and 15 are presently examined on the merits as new claims.

3. The examiner acknowledges applicant's amendments to claims 17-20 concerning their previous dependency on erroneously withdrawn claim 15 as noted above. Thus, claims 17-20 are presently examined on the merits as new claims.

4. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

5. This application contains claims 28-42 and 44-68 drawn to an invention nonelected with traverse in Paper No. 20060717. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

7. The information disclosure statement(s) (IDS) submitted on 08/07/2006 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Specification

8. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

9. Claims 44-47 are objected to because of the following informalities: dependency from canceled claim 43. Appropriate correction is required.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1-6, 8-9, 11-12, 14-15, and 17-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 2004/0111041 A1). Ni et al discloses a method, comprising:

- monitoring a plurality of physiological parameters of a patient via a medical device (100, 200 and 300), wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity (abstract and paragraph 0034);
- determining when the patient is attempting to sleep (abstract);
- determining values of at least one sleep quality metric (paragraphs 0006, 0007, and 0025) that is indicative of sleep quality based on at least one of the physiological parameters, a determination that the patient is attempting to sleep, on the determined activity level; and
- periodically determining an activity level of the patient based on at least one of the physiological parameters and a determination that the patient is not attempting to sleep (paragraphs 0034 and 0035).

12. For claim 2, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the sensed activity levels via sensor 103) from the patient that the patient is attempting to sleep (paragraph 0035).

13. For claims 3 and 4, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep comprises determining when the patient is recumbent (paragraphs 0055 and 0056) and (b) a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent comprises determining when the patient is recumbent based on a DC component of each of the signals (paragraphs 0055 and 0056).

14. For claims 5 and 6, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (abstract) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (abstract and paragraphs 0055 and 0056).

15. For claims 8 and 9, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood pressure (paragraphs 0034, 0055 and 0056).

16. For claim 11, Ni et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the

physiological parameters; and determining an amount of time between the first and second times (paragraphs 0055 and 0056).

17. For claim 12, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is asleep based on at least one of the physiological parameters (abstract); and determining an amount of time that the patient is asleep during a period (paragraphs 0055 and 0056).

18. For claim 14, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is within a sleep state based on at least one of the physiological parameters (abstract); and determining an amount of time that the patient was within the sleep state (paragraphs 0055 and 0056).

19. For claim 15, Ni et al discloses a method wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state (paragraphs 0003 and 0004).

20. For claim 17, Ni et al discloses a method wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels (paragraphs 0070 and 0075).

21. For claim 18, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing the at least one of the mean and the median activity level to at least one threshold; and selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison (paragraphs 0070 and 0075).

22. For claim 19, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and

determining at least one of a percentage of time above the threshold and a percentage of time below the threshold (paragraphs 0055 and 0056).

23. For claim 20, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and determining an average length of time that consecutively determined activity levels were above the threshold (paragraphs 0055 and 0056).

24. For claims 21-23, Ni et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (Figures 7-9); (b) a medical device delivers a therapy (paragraph 0041) to the patient according to a plurality of therapy parameter sets, the method further comprising: associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set; for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set as best seen in Figure 2; and (c) presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values (paragraphs 0053-0056).

25. For claim 25, Ni et al discloses a method wherein a medical device comprises an implantable medical device (paragraph 0029).

26. For claims 26 and 27, Ni et al the claimed methods of using an implantable medical device including an implantable neurostimulator (10) for implanting and/or utilizing a drug pump.

Response to Arguments

27. Applicant's arguments with respect to claims 1-6, 8, 9, 11, and 21-27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

28. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JH

MAIL STOP AF
RESPONSE UNDER 37 C.F.R. 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP 3736

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Kenneth T. Heruth; Keith A. Miesel	Confirmation No.	8230
Serial No.:	10/825,955		
Filed:	April 15, 2004	Customer No.:	28863
Examiner:	Jeffrey Gerben Hoekstra		
Group Art Unit:	3736		
Docket No.:	1023-362US01		
Title:	COLLECTING ACTIVITY AND SLEEP QUALITY INFORMATION VIA A MEDICAL DEVICE		

AMENDMENT

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Final Office Action mailed January 17, 2007, the period of response for which runs through April 17, 2007, please amend the application as follows.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks begin on page 9 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

Claim 1 (Currently Amended): A method comprising:

monitoring a plurality of physiological parameters of a patient via a medical device, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity;

determining when the patient is attempting to sleep;

determining values of at least one sleep quality metric that is indicative of sleep quality based on values of at least one of the physiological parameters ~~and a determination that~~ when the patient is attempting to sleep;

periodically determining an activity level of the patient based on at least one of the physiological parameters ~~and a determination that the patient is not attempting to sleep~~; and

determining a value of at least one activity metric based on ~~the determined~~ activity levels determined when the patient is not attempting to sleep.

Claim 2 (Original): The method of claim 1, wherein determining when the patient is attempting to sleep comprises receiving an indication from the patient that the patient is attempting to sleep.

Claim 3 (Original): The method of claim 1, wherein monitoring a plurality of physiological parameters comprising monitoring at least one signal that indicates posture of the patient, and determining when the patient is attempting to sleep comprises determining when the patient is recumbent.

Claim 4 (Original): The method of claim 3, wherein monitoring at least one signal comprises monitoring a signal from each of a plurality of orthogonally aligned accelerometers, and determining when the patient is recumbent comprises determining when the patient is recumbent based on a DC component of each of the signals.

Claim 5 (Original): The method of claim 1, wherein determining when the patient is attempting to sleep comprises determining when the patient is attempting to sleep based on a physical activity level of the patient.

Claim 6 (Currently Amended): The method of claim 5, wherein determining when the patient is attempting to sleep based on an activity level comprises:

comparing the activity level to an activity level threshold; and

comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold.

Claim 7 (Withdrawn): The method of claim 1, wherein monitoring a plurality of physiological parameters comprising monitoring a level of melatonin within a bodily fluid, and determining when the patient is attempting to sleep comprises determining when the patient is attempting to sleep based on the melatonin level.

Claim 8 (Previously Presented): The method of claim 1, wherein monitoring a plurality of physiological parameters comprises monitoring at least one of posture, heart rate, respiration rate, respiratory volume, or core temperature.

Claim 9 (Previously Presented): The method of claim 1, wherein monitoring a plurality of physiological parameters comprises monitoring at least one of blood pressure, blood oxygen saturation, partial pressure of oxygen within blood, partial pressure of oxygen within cerebrospinal fluid, muscular activity, arterial blood flow, or galvanic skin response.

Claim 10 (Withdrawn): The method of claim 1, wherein the sleep quality metric comprises sleep efficiency, and determining values of the sleep quality metric comprises:

determining when the patient is asleep based on at least one of the physiological parameters; and

determining a percentage of time that the patient is asleep while the patient is attempting to sleep.

Claim 11 (Original): The method of claim 1, wherein the sleep quality metric comprises sleep latency, and determining values of the sleep quality metric comprises:

identifying a first time when the patient is attempting to fall asleep;

identifying a second time when the patient falls asleep based on at least one of the physiological parameters; and

determining an amount of time between the first and second times.

Claim 12 (Original): The method of claim 1, wherein determining values of the sleep quality metric comprises:

identifying when the patient is asleep based on at least one of the physiological parameters; and

determining an amount of time that the patient is asleep during a period.

Claim 13 (Withdrawn): The method of claim 1, wherein determining values of the sleep quality metric comprises:

identifying when the patient is asleep based on at least one of the physiological parameters; and

identifying at least one of a number of arousal events and a number of apnea events during a period of sleep.

Claim 14 (Original): The method of claim 1, wherein determining values of the sleep quality metric comprises:

identifying when the patient is within a sleep state based on at least one of the physiological parameters; and

determining an amount of time that the patient was within the sleep state.

Claim 15 (Original): The method of claim 14, wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state.

Claim 16 (Cancelled).

Claim 17 (Previously Presented): The method of claim 1, wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels.

Claim 18 (Original): The method of claim 17, wherein determining a value of an activity metric comprises:

comparing the at least one of the mean and the median activity level to at least one threshold; and

selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison.

Claim 19 (Previously Presented): The method of claim 1, wherein determining a value of an activity metric comprises:

comparing each of the activity levels to a threshold value; and

determining at least one of a percentage of time above the threshold and a percentage of time below the threshold.

Claim 20 (Previously Presented):The method of claim 1, wherein determining a value of an activity metric comprises:

comparing each of the activity levels to a threshold value; and

determining an average length of time that consecutively determined activity levels were above the threshold.

Claim 21 (Original): The method of claim 1, wherein periodically determining an activity level comprises periodically determining a number of activity counts.

Claim 22 (Original): The method of claim 1, wherein the medical device delivers a therapy to the patient according to a plurality of therapy parameter sets, the method further comprising:

associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set;

for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and

for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

Claim 23 (Original): The method of claim 22, further comprising presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values.

Claim 24 (Original): The method of claim 23, further comprising ordering the list of therapy parameter sets according to values of a user selected one of the sleep quality metrics and activity metrics.

Claim 25 (Original): The method of claim 1, wherein the medical device comprises an implantable medical device.

Claim 26 (Previously Presented): The method of claim 25, wherein the implantable medical device comprises at least one of an implantable neurostimulator and an implantable drug pump.

Claim 27 (Original): The method of claim 1, wherein the medical device comprises at least one of a trial neurostimulator and a trial pump.

Claims 28-68 (Cancelled).

Claim 69 (New): A method comprising:

monitoring a plurality of physiological parameters of a patient via a medical device, wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity;

determining when the patient is attempting to sleep;

determining values of at least one sleep quality metric that is indicative of sleep quality based on values of at least one of the physiological parameters when the patient is attempting to sleep;

periodically determining an activity level of the patient based on at least one of the physiological parameters;

associating each of the determined sleep quality metric values and each of the activity levels determined when the patient is not attempting to sleep with a current therapy parameter set;

for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and

for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

Claim 70 (New): The method of claim 69, further comprising presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values.

Claim 71 (New): The method of claim 71, further comprising ordering the list of therapy parameter sets according to values of a user selected one of the sleep quality metrics and activity metrics.

REMARKS

This Amendment is responsive to the Final Office Action dated January 17, 2007. Claims 1 and 6 have been amended. Claims 28-42 and 44-68, which were previously withdrawn, have now been cancelled. New claims numbered 69-71 have been added. Claims 1-15, 17-27 and 69-71 are pending, with claims 7, 10 and 13 withdrawn due to restriction.

Applicant respectfully requests entry of the after-final claim amendments and additions. The amendments are minor in that they either correct grammatical errors or merely provide greater clarity. The new claims recite limitations found in the claims as previously presented. Accordingly, Applicant respectfully submits the amended and new claims raise no new issues, and required no further search. Further, Applicant respectfully submits that the amended and new claims are in condition for allowance, or at least are in better form for appeal relative to the claims as previously presented.

Claim Objections

The Final Office Action objected to claims 44-47 because they depended upon cancelled claim 43. Applicant has cancelled claims 44-47, which were previously withdrawn due to restriction, without prejudice or disclaimer. Accordingly, this objection is moot.

Claim Rejection Under 35 U.S.C. § 102(e)

The Final Office Action rejected claims 1-6, 8, 9, 11, 12, 14, 15 and 17-27 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111041, herein referred to as Ni). Applicant respectfully traverses the rejection. Ni fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Ni fails to disclose or suggest determining when a patient is attempting to sleep, as recited by independent claim 1. Instead, Ni describes detecting when a patient is sleeping by detecting sleep onset and termination. The system described by Ni compares a sleep-related signal to a threshold value and detects sleep based on the comparison. Ni does not disclose or suggest determining when a patient is attempting to sleep. As one example, the

system of Ni does not disclose or suggest detecting when a patient is awake but attempting to sleep. Ni is limited to determining whether a patient is sleeping.

Furthermore, Ni fails to disclose or suggest determining a value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep, as recited by independent claim 1 as amended. As discussed above, Ni does not determine when a patient is attempting to sleep. Moreover, contrary to the requirements of amended claim 1, Ni is focused on monitoring activity to determine when the patient falls asleep and wakes up. In other words, the Ni system looks at activity when the patient is not asleep to determine when the patient falls asleep. Merely looking at activity to determine when the patient falls asleep is clearly not the same as determining an activity metric value based on activity levels when the patient is not attempting to sleep. This teaching of Ni would not have even suggested determining the value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep.

As another example, with respect to claim 11, Ni fails to disclose or suggest that the sleep quality metric comprises sleep latency, and determining values of the sleep quality metric comprises identifying a first time when the patient is attempting to fall asleep, identifying a second time when the patient falls asleep based on at least one of the physiological parameters, and determining an amount of time between the first and second times. Ni does not disclose or suggest identifying a first time when the patient is attempting to fall asleep. Ni merely describes identifying when the patient falls asleep. For at least these reasons, Ni clearly fails to disclose or suggest determining an amount of time between a first time when the patient is attempting to fall asleep and a second time when the patient falls asleep.

As another example, Ni fails to disclose or suggest selecting an activity metric value from a plurality of predetermined possible values, as recited in claim 18. Paragraphs [0070] and [0075] of Ni discuss a moving average of activity, and comparison to the threshold value, but do not in any way suggest selection of an activity metric value from a plurality of predetermined possible values.

Further, with respect to claim 19, Ni does not disclose or suggest determine a percentage of time that activity levels were above or threshold, or determining a percentage of time that activity levels were below a threshold. Paragraphs [0055] and [0056] of Ni do teach comparison

to a threshold to determine amounts of time sleeping, but do not suggest determining a percentage of time above or below a threshold.

Also, with respect to Applicant's claim 22, Ni fails to disclose or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set, and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set.

Ni does not disclose or suggest associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set. Ni merely describes determining therapy parameters based on whether or not the patient is sleeping. As one example, Ni describes adjusting a lower rate limit of a pacemaker based on recognition of sleep or non-sleep states.[1] In contrast, Applicant's claim 22 requires that, when a sleep quality metric value or an activity level is determined, the therapy parameter set that was currently used to deliver stimulation is associated with the sleep quality metric value or activity level. In this manner, sleep quality and activity metrics may be used to, evaluate the effectiveness of the therapy parameters in some embodiments according to the claim.[2]

Further, with respect to claim 23, Ni does not disclose or suggest a list of therapy parameter sets with associated sleep and activity metrics. As discussed above, Ni does not suggest association of determined sleep and activity metrics with the therapy parameter set active when the metric was determined, e.g., for the purpose of evaluating the therapy parameter sets. Additionally, although paragraphs [0053]-[0056] mention historical sleep information and programming commands, they do not in any way describe or imply a list of therapy parameter sets. The mere mention of programming commands and historical sleep information does not suggest a list of therapy parameter sets with associated sleep and activity metrics.

Moreover, Ni does not in any way suggest ordering a list of therapy parameter sets, as recited in claim 24. The Final Office Action did not discuss claim 24, or in any way explain how

[1] Ni, paragraph [0026].
[2] *See* Summary of Invention of present application.

Ni could be considered applicable to its requirements. **Applicant respectfully suggests that the rejection of claim 24 must be withdrawn or explained in any subsequent Office Action.** In other words, Applicant respectfully suggests that an Advisory Action should not be issued without a withdrawal or explanation of the rejection of claim 24.

Ni also fails to disclose or suggest a medical device comprising at least one of a trial neurostimulator and a trial pump, as recited by claim 27. Ni makes no mention of a trial neurostimulator or a trial pump. Instead, Ni describes implementing sleep detection methods within a cardiac rhythm management system or hypoglossal nerve stimulator.[3] Ni does not disclose or suggest a trial neurostimulator or a trial pump.

In order to support an anticipation rejection under 35 U.S.C. § 102(e), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."[4] If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(e) is improper.[5]

Ni fails to disclose each and every limitation set forth in independent claim 1. Claims 2-6, 8, 9, 11, 12, 14, 15 and 17-27 are dependent upon claim 1 and are also in condition for allowance. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 1-6, 8, 9, 11, 12, 14, 15 and 17-27 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

New Claims

Applicant has added new claims 69-71 to the present application. Ni does not disclose or suggest the requirements of the new claims. For example, as discussed above with respect to claim 22, Ni does not disclose or suggest associating each of the determined sleep quality metric values and each of the activity levels determined when the patient is not attempting to sleep with a current therapy parameter set, for each of the plurality of therapy parameter sets, determining a

[3] Ni, paragraph [0033].
[4] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").
[5] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set, as required by new independent claim 69. No new matter is added by claim 69.

CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not necessarily admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: 3-19-07

By: _____

SHUMAKER & SIEFFERT, P.A.
1625 Radio Drive, Suite 300
Woodbury, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

Name: Jason D. Kelly
Reg. No.: 54,213

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,955	04/15/2004	Kenneth T. Heruth	1023-362US01	8230

28863 7590 06/27/2007

SHUMAKER & SIEFFERT, P. A.
1625 RADIO DRIVE
SUITE 300
WOODBURY, MN 55125

EXAMINER	
HOEKSTRA, JEFFREY GERBEN	
ART UNIT	PAPER NUMBER
3736	

D. 9-27-07 bmd dk

MAIL DATE	DELIVERY MODE
06/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/825,955	HERUTH ET AL.	
	Examiner	Art Unit	
	Jeffrey G. Hoekstra	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,17-27 and 69-71* is/are pending in the application.

4a) Of the above claim(s) *7,10,13,24 and 71* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,12,14,15,17-23,25-27,69 and 70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20070102*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/13/2007 has been entered.

Notice of Amendment

2. In response to the amendment filed on 04/13/2007, amended claim(s) 1, canceled claim(s) 16 and 28-68, and new claim(s) 69-71 is/are acknowledged. The current rejections of the claim(s) 1-6, 8, 9, 11, and 17-27 is/are *withdrawn*. The following new and reiterated grounds of rejection are set forth:

Election/Restrictions

3. Claims 24 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 06/30/2006.

4. The Examiner notes claims 24 and 71 are withdrawn from further consideration as being drawn to nonelected Species AA" "user-interface" embodiment.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

6. The information disclosure statement(s) (IDS) submitted on 01/02/2007 is/are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statement(s).

Claim Objections

7. Claim 3 is objected to because of the following informalities: the positive recitation of "comprising" in line 2 appears to be a typographical and/or grammatical error. The Examiner notes it appears Applicant intended it to positively recite "comprises". Appropriate correction is required.

8. Claim 69 is objected to because of the following informalities: the positive recitation of "each of the plurality of therapy parameter sets" in lines 14 and 17 appears to lack antecedent basis and may render the claim indefinite. Appropriate correction is required.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 69 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: (a) the structural relationship between the "values of at least one sleep quality metric" of line 6 and the "value of each of the least one sleep quality metric" of lines 14-15 and (b) the structural relationship between the "values of at least one sleep quality metric" of line 6 and the "at least one activity metric value" of lines 17-18. Although it is clear that the second recitations are associated with the therapy parameter set, it is indefinite if the values in both cases (a) and (b) are distinct limitations or if they are duplicate structure and in the event that they are distinct limitations how they differ.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-23, 25-27, 69, and 70 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al. (US 2004/0111040 A1).

14. Claims 1-3, 5, 6, 8-9, 11-12, 14-15, and 17-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Ni et al (US 2004/0111041 A1).

15. For claims 1 and 69, Ni et al discloses a method, comprising:

- monitoring a plurality of physiological parameters (620, 625, and 630) of a patient via an implantable medical device (100, 200 and 300), wherein the plurality of physiological parameters includes at least one parameter indicative of patient physical activity (e.g. at least breathing or posture) (paragraphs 39, 52, and 77);
- determining when the patient is attempting to sleep via sensors (130, 134, 320, and 321) (as best seen in Figures 5B and 6) (paragraphs 7, 11, 53-57, 77, and 84-90);
- determining values of at least one sleep quality metric (550) that is indicative of sleep quality based on values of the at least one physiological parameters when the patient is attempting to sleep (565) (as best seen in Figure 5A) (paragraphs 47-48, 53-57, and 84-90);
- periodically determining an activity level (paragraphs 42-43 and 51) of the patient based on the at least one physiological parameters and a determination that the patient is not attempting to sleep (570) (paragraph 106);
- determining a value of at least one activity metric based on the activity levels determined when the patient is not attempting to sleep (paragraphs 132-134); and
- associating the sleep quality metrics and the activity level metrics with a therapy parameter set (587 and 597) via elements 340 and 350 (paragraphs 62-63 and 72).

16. For claim 2, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises receiving an indication (the patients sensed activity levels as cited above) that the patient is attempting to sleep (paragraph 106).

17. For claim 3, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprising monitoring (a) at least one signal that indicates posture of the patient and determining when the patient is attempting to sleep comprises determining when the patient is recumbent (as best seen in Figures 5B and 6) (paragraphs 97, 106, and 119).

18. For claims 5 and 6, Ni et al discloses a method wherein determining when the patient is attempting to sleep comprises: (a) determining when the patient is attempting to sleep based on a physical activity level of the patient (Figures 5B and 6) (paragraphs 11, 77, and 95-97) and (b) comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold (paragraphs 48, 57, 84-85 and 95).

19. For claims 8 and 9, Ni et al discloses a method wherein monitoring a plurality of physiological parameters comprises monitoring posture and blood pressure (paragraph 52).

20. For claim 11, Ni et al discloses a method wherein the metric indicative of sleep quality comprises sleep latency, and determining values of the sleep quality metric comprises: identifying a first time when the patient is attempting to fall asleep; identifying a second time when the patient falls asleep based on at least one of the

physiological parameters; and determining an amount of time between the first and second times (as best seen in Figures 7A, 7B9, 14, and 15).

21. For claim 12, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is asleep based on at least one of the physiological parameters (510); and determining an amount of time that the patient is asleep during a period (as best seen in Figures 7A, 7B9, 14, and 15).

22. For claim 14, Ni et al discloses a method wherein determining values of the sleep quality metric comprises: identifying when the patient is within a sleep state based on at least one of the physiological parameters (510); and determining an amount of time that the patient was within the sleep state (as best seen in Figures 7A, 7B9, 14, and 15).

23. For claim 15, Ni et al discloses a method wherein the sleep state comprises at least one of an S3 sleep state and an S4 sleep state (paragraphs 2-4).

24. For claim 17, Ni et al discloses a method wherein determining a value of an activity metric comprises determining at least one of a mean and a median of determined activity levels (paragraphs 46 and 99).

25. For claim 18, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing the at least one of the mean and the median activity level to at least one threshold (paragraph 99); and selecting the activity metric value from a plurality of predetermined possible activity metric values based on the comparison (paragraphs 47 and 92).

26. For claim 19, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and

determining at least one of a percentage of time above the threshold and a percentage of time below the threshold (paragraphs 46 and 99) (as best seen in Figures 7A, 7B9, 14, and 15).

27. For claim 20, Ni et al discloses a method wherein determining a value of an activity metric comprises: comparing each of the activity levels to a threshold value; and determining an average length of time that consecutively determined activity levels were above the threshold (paragraphs 46 and 99) (as best seen in Figures 7A, 7B9, 14, and 15).

28. For claims 21-23 and 70, Ni et al discloses a method wherein (a) periodically determining an activity level comprises periodically determining a number of activity counts (as best seen in Figures 7A, 7B9, 14, and 15); (b) the medical device delivers a therapy (paragraphs 72-74) to the patient according to a plurality of therapy parameter sets, the method further comprising: associating each of the determined sleep quality metric values and each of the determined activity levels with a current therapy parameter set; for each of the plurality of therapy parameter sets, determining a representative value of each of the at least one sleep quality metric based on the sleep quality metric values associated with the therapy parameter set; and for each of the plurality of therapy parameter sets, determining at least one activity metric value based on the activity levels associated with the therapy parameter set; and (c) presenting a list of the therapy parameter sets, associated representative sleep quality metric values, and associated activity metric values (paragraphs 75-76).

29. For claim 25, Ni et al discloses a method wherein a medical device comprises an implantable medical device (paragraph 11).

30. For claims 26 and 27, Ni et al the claimed methods of using an implantable medical device including an implantable neurostimulator (202).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

32. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

33. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ni et al in view of Sheldon (US 5,593,431). Ni et al discloses the claimed invention, including monitoring posture via accelerometers, except for explicitly disclosing monitoring a signal from each of a plurality of orthogonally aligned accelerometers and determining when the patient is recumbent based on a DC component of each of the signals.

Sheldon teaches a medical device comprising monitoring a signal from each of a plurality of orthogonally aligned accelerometers and determining when the patient is recumbent based on a DC component of each of the signals (abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the medical device as taught by Ni et al, with the medical device as taught by Sheldon for the purpose of monitoring posture.

Response to Arguments

34. Applicant's arguments with respect to claims 1-6, 8, 9, 11, 12, 14, 15, 17-23, 25-27, 69, and 70 have been considered but are moot in view of the new ground(s) of rejection.

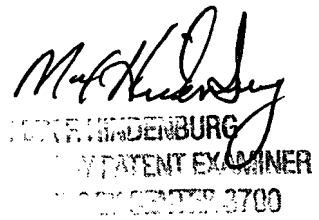
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey G. Hoekstra whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday, 8:00 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max F. Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J.H./
Jeff Hoekstra
Examiner, Art Unit 3736



Date Mailed: January 2, 2007

Form 1449* INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION (Use several sheets if necessary)	Docket Number: 1023-362US01	Application Number: 10/825,955
	Applicant: Kenneth T. Heruth; Keith A. Miesel	
	Filing Date: April 15, 2004	Group Art Unit: 3736
	Examiner Name: Jeffrey Gerben Hoekstra	

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number	Issue/Document Publication Date	Name	Filing Date If Appropriate
/JH/	5,514,162	05/07/1996	Bomzin et al.	
/JH/	2004/0111040 A1	06/10/2004	Ni et al.	
/JH/	6,890,306 B2	05/10/2005	Poezevera	

FOREIGN PATENT DOCUMENTS

Examiner Initial	Document Number	Publication Date	Country	Translation Yes	Translation No

OTHER DOCUMENTS (Including Authors, Title of Item, Page(s), Vol/Issue No., Publisher, Place of Publication)

EXAMINER	Date Considered
/Jeffrey Hoekstra/	06/21/2007

*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Based on Form PTO-FB-A820
(Also form PTO-1449)

Patent and Trademark Office, U.S. Department of Commerce